IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION, and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, *Plaintiffs*, v. MYLAN PHARMACEUTICALS INC., MYLAN INC., and MYLAN LABORATORIES LIMITED, *Defendants.*	C.A. NO. 1:20-CV-19 (TSK) (LEAD) *Consolidated with* C.A. No. 1:20-cv-90

JOINT STIPULATION AND [PROPOSED] ORDER REGARDING ADMISSIBILITY OF DOCUMENTS

Plaintiffs Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International GMBH, Boehringer Ingelheim Corporation, and Boehringer Ingelheim Pharma GMBH & Co. KG, (collectively, "Plaintiffs"), and Defendants Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan Laboratories Limited, (collectively, "Defendants" and with Plaintiffs, the "parties") hereby stipulate and agree as follows:

IT IS HEREBY STIPULATED AND AGREED, by and between the undersigned parties, for purposes of this litigation only, and subject to the Court's approval:

1. Any certified or publicly available document created or issued by the United States Patent and Trademark Office ("PTO") and any such documents produced by the parties in this

litigation constituting the patents-in-suit, file histories of the patents-in-suit, assignments of the patents-in-suit, any filing before the PTO, and any correspondence to or from the PTO concerning any such filing, shall be deemed prima facie authentic for purposes of admissibility at trial, with no need for additional proof of authenticity at trial, provided that the trial exhibit appears to be unaltered from the condition in which the document was created or issued by the PTO or produced by the producing party.

2. Any certified or publicly available document created or issued by the PTO and any such documents produced in this litigation by the parties constituting the patents-in-suit, file histories of the patents-in-suit, assignments of the patents-in-suit, any filing before the PTO, and any correspondence to or from the PTO concerning any such filing, shall be deemed a "business record" or "public record" that meets the requirements of Fed. R. Evid. 803(6) and 803(8) and therefore is not subject to exclusion from evidence at trial on grounds of hearsay, provided that the trial exhibit appears to be unaltered from the condition in which the document was created or issued by the PTO or produced by the producing party.

3. Any document or publications submitted to, or created or issued by the U.S. Food and Drug Administration ("FDA") (including New Drug Applications ("NDA"), Investigational New Drug Applications ("IND"), Abbreviated New Drug Applications ("ANDAs"), any supplements or amendments thereto, any FDA drug approval or review package, including clinical or medical reviews, and any other part of a FDA regulatory file), and any such documents produced in this matter by the parties, including but not limited to those that constitute correspondence to or from the FDA concerning any such regulatory filing, shall be deemed prima facie authentic for purposes of admissibility at trial, provided that the trial exhibit appears to be

unaltered from the condition in which the document was submitted to, or created or issued by the FDA or produced by the producing party.

4. Any document or publications submitted to, or created or issued by the FDA that constitutes a regulatory filing before the FDA (including NDAs, INDs, ANDAs, any supplements or amendments thereto, and any FDA drug approval or review package, including clinical or medical reviews, and any other part of a FDA regulatory file), and any such document produced in this matter by the parties including but not limited to those that constitute correspondence to or from the FDA concerning any such regulatory filing, shall be deemed a "business record" and/or a "public record" that meets the requirements of Fed. R. Evid. 803(6) and/or 803(8) therefore is not subject to exclusion from evidence at trial on grounds of hearsay, provided that the trial exhibit appears to be unaltered from the condition in which the document was submitted to, or created or issued by the FDA or produced by the producing party.

5. Any document produced in this litigation by the parties and bearing indicia that it was prepared or kept by the producing party in the normal course of business and not for purposes of litigation shall be prima facie authentic and a "business record" that meets the requirements of Fed. R. Evid. 803(6), and therefore is not subject to exclusion from evidence at trial on grounds of hearsay. No additional proof of authenticity or 'business record" status will be required at trial, provided that the trial exhibit appears to be unaltered from the condition in which the document was produced by the producing party.

6. The parties agree that it is the producing party's burden to come forward with evidence of the lack of authenticity of its own documents and things and evidence that the documents described above are not subject to a hearsay exception based on business records or party admissions.

7. The parties agree to meet and confer in good faith regarding any disputes regarding documents and things presumed to be authentic and within the scope of Fed. R. Evid. 803(6) under the terms of this Stipulation.

8. To promote efficiency and conserve the Court's time, if either party seeks to move any of the documents identified in this stipulation into evidence using an expert, the parties agree not to object on the grounds of lack of foundation, except that the parties reserve the right to object on the grounds of lack of foundation to any document referenced by an expert witness which was not previously addressed in a report written by the expert witness and served in accordance with Federal Rule of Civil Procedure 26(a)(2)(B) in this case.

9. The parties reserve all other objections to the admissibility of exhibits, including on the basis of Fed. R. Evid. 401 and 403.

Dated: April 24, 2025

SO ORDERED, this _____ day of _____, 2025.

_____
Thomas S. Kleeh, Chief Judge
Northern District of West Virginia

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